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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/736,004	12/15/2003	Yi Feng Zheng	7459	2953

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EXAMINER

HAQ, SHAFIQL

ART UNIT PAPER NUMBER

1641

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/736,004

Applicant(s)

ZHENG ET AL.

Examiner

Shafiqul Haq

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 13-25, 27, 30 and 31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 13-25, 27 and 30-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection (2/6/06). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/9/06 has been entered.
2. Claims 7-12, 26, 28-29 and 32 have been cancelled.
3. Claims 1-6 and 13-25, 27 and 30-31 are pending and under active prosecution.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Avenia et al. (US 4,041,076).

Claims recite compound of formula I, immunogen and antibody against the compound.

Avenia et al. disclose phenethylamine compounds (see formula II and III), immunogen and antibodies against them (see description of invention in column 1 and 2). Formula I and II of the reference anticipate Formula I compound of present

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application when in referenced compound R_5 =hydroxyl or lower alkoxy; R_1 , R_3 =H; R_2 =methyl; R_4 , R'_4 =H or methyl and $n=1-3$. Avenia et al. disclose that immunogenic carrier can be coupled to free acid (carboxyl functional group of formula II) or the carboxyl functional group of the hapten can be activated with N-hydroxysuccinimide (NHS) ester for efficient coupling of immunogenic carrier material at this site (column 2, lines 10-13, 37-58 and lines 66-2 of columns 2-3). Avenia et al. disclose that the carrier can be a polyamino acid or a protein (e.g. albumin, BSA, or polyamino acids) (column 2, lines 19-36). Avenia et al. also disclose antibodies raised against compounds of formula I (column 4, lines 24-37). Furthermore, labeled conjugate of the hapten with detectable label (e.g. radioisotope, enzyme, fluorophores etc) is also disclosed (column 4, lines 35-58).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 13-25, 27 and 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hui et al. (EP 1340981 A2) in view of Avenia et al. (US 4,041,076).

Claims recite methods, compositions and kits for detecting the presence and/or amounts of entactogens in samples.

Hui et al. disclose various competitive and noncompetitive methods/assays and a kit for detection and quantitative determination of amphetamine derivatives such as MDA, MDMA, MDEA, MDPA, BDB, MBDB etc (paragraphs [0012], [0024], [0029], [0064-0067], [0059] and [0060]) using antibody against amphetamine derivatives and label derivatives (such as fluorescent, luminescent, radioactive isotope etc.) (paragraph [0022]).

Hui's amphetamine derivatives and immunogens are similar to the compound and immunogen of the present invention and are expected to recognize different amphetamine derivatives suitable for different immunoassays. However, the linking group or the position of linker at the amphetamine derivative is different from the present compound.

Avenia et al. disclose amphetamine immunogen, labeled tracer and antibodies (see the teaching of Avenia in above paragraph 5) and disclose competitive immunoassay method for detection of phenethylamines (e.g. norepinephrine, dopamine, epinephrine and amphetamines). The immunogen of Avenia et al. is the same as the immunogen of present application.

Since detection of amphetamine, methamphetamine and their derivatives is important in the field of ecstasy drug and once a hapten, immunogen or an antibody is available, one would obviously try to use the hapten and the immunogen in different immunoassay methods to develop a better detection assay for the drug.

Therefore, given the above fact, it would have been obvious at the time of the invention to a person of ordinary skill in the art to substitute equivalent hapten,

immunogen or antibody as disclosed by Avenia et al in the method of Hui et al, with the expectation of obtaining a similarly useful immunoassay method and kit for detection of amphetamine and amphetamine derivatives.

8. Claims 13-25, 27 and 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rouhani et al. (GB 2361473 A) in view of Avenia et al. (US 4,041,076).

Claims recite methods, compositions and kits for detecting the presence and/or amounts of entactogens in samples.

Rouhani et al. disclose a method for detection of ecstasy-class analogs. Rouhani discloses preparation of antibody (page 6, lines 19-24; pages 16-18) using the compound conjugated with carrier protein (see abstract) and different homogeneous and heterogeneous immunoassay methods (pages 8-9 and 34) and assay kit (page 31, lines 9-12 and claim 10) for detection and quantitation of ecstasy-class analogs in biological samples (page 22, lines 19-24). Rouhani also discloses the above compound conjugated with a protein to be adapted as immunogen (page 41, example 7). Attachment to a carrier protein or a label is also inherent in the process of immunization (see claims 7 and 8) and immunoassay methods (see pages 8-9 and 34) as disclosed in this reference.

Rouhani's amphetamine and methamphetamine derivatives and immunogens are similar to the compound and immunogen of the present invention and are expected to recognize different amphetamine derivatives suitable for different

immunoassays. However, the linking group or the position of linker at the amphetamine derivative is different from the present compound.

Avenia et al. disclose amphetamine immunogen, labeled tracer and antibodies (see the teaching of Avenia in above paragraph 5) and disclose competitive immunoassay method for detection of phenethylamines (e.g. norepinephrine, dopamine, epinephrine and amphetamines). The immunogen of Avenia et al. is the same as the immunogen of present application.

Sine detection of amphetamine, methamphetamine and their derivatives is important in the field of ecstasy drug and once a hapten, immunogen or an antibody is available, one would obviously try to use the hapten and the immunogen in different immunoassay methods to develop a better detection assay for the drug.

Therefore, given the above fact, it would have been obvious at the time of the invention to a person of ordinary skill in the art to substitute equivalent hapten, immunogen or antibody as disclosed by Avenia et al in the method of Rouhani et al, with the expectation of obtaining a similarly useful immunoassay method and kit for detection of amphetamine and amphetamine derivatives.

Response to Argument

9. Applicant's arguments and affidavit filed under 37 CFR 1.131 on 5/9/06 have been fully considered, and are persuasive to overcome the rejections of 2/6/06 under 35 USC 112, 35 USC 102 and 35 USC 103, but a further search necessitated applying new art under 35 USC 102 and 35 USC 103 as described in above paragraphs 4-8.

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Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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